

We claim:

1. A crystalline donepezil hydrochloride form H1, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 15.2, 18.7, 20.6, 22.3, 23.5, 24.0, 24.6, 27.0, 29.0 and 30.5 degrees.
2. A crystalline donepezil hydrochloride form H1, further characterized by an x-ray powder diffraction spectrum as in figure 1.
3. A process for preparation of donepezil hydrochloride form H1 as defined in claim 1, which comprises the steps of:
  - a) dissolving donepezil free base in methylene dichloride;
  - b) adding hydrochloric acid; and
  - c) precipitating donepezil hydrochloride form H1 from the solution formed in (b) by adding an anti-solvent.
4. A process according to claim 3, wherein the anti-solvent is diisopropyl ether, n-hexane, n-heptane or diethyl ether.
5. A process according to claim 3, wherein the anti-solvent is diisopropyl ether.
6. An another process for preparation of donepezil hydrochloride form H1 as defined in claim 1, which comprises the steps of:
  - a) dissolving donepezil hydrochloride in methylene dichloride; and
  - b) precipitating donepezil hydrochloride form H1 from the solution formed in (a) by adding an anti-solvent.
7. A process according to claim 6, wherein the anti-solvent is diisopropyl ether, n-hexane, n-heptane or diethyl ether.
8. A process according to claim 6, wherein the anti-solvent is diisopropyl ether.
9. A crystalline donepezil hydrochloride form H2, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 6.6, 6.8, 10.1, 12.8, 13.7, 15.0, 15.6, 16.5, 17.3, 18.4, 19.5, 19.8, 20.0, 21.6, 21.9, 22.3, 23.9, 24.2, 24.7, 25.3, 26.0, 26.9 and 28.2 degrees.
10. A crystalline donepezil hydrochloride form H2 as defined in claim 9, further characterized by an x-ray powder diffraction spectrum as in figure 2.
11. A process for preparation of donepezil hydrochloride form H2 as defined in claim 9, which comprises the steps of:
  - a) dissolving donepezil free base in toluene;
  - b) adding hydrochloric acid; and

- c) isolating donepezil hydrochloride form H2 by filtration or centrifugation.
12. A crystalline donepezil hydrochloride monohydrate, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 5.0, 10.0, 12.7, 13.2, 16.2, 20.0, 21.3, 23.1, 23.9 and 25.3 degrees.
- 5 13. A crystalline donepezil hydrochloride monohydrate as defined in claim 12, further characterized by an x-ray powder diffraction spectrum as in figure 3.
14. A process for preparation of donepezil hydrochloride monohydrate as defined in claim 12, which comprises the steps of:
- a) dissolving donepezil free base in a mixture of chloroform and water;
- 10 b) adding hydrochloric acid; and
- c) precipitating donepezil hydrochloride monohydrate from the solution formed in (b) by adding an anti-solvent.
- 15 15. A process according to claim 14, wherein the anti-solvent is diisopropyl ether, n-hexane, n-heptane or diethyl ether.
16. A process according to claim 14, wherein the anti-solvent is diisopropyl ether.
17. An another process for preparation of donepezil hydrochloride monohydrate as defined in claim 12, which comprises the steps of:
- a) dissolving donepezil hydrochloride in a mixture of chloroform and water; and
- 20 b) precipitating donepezil hydrochloride monohydrate from the solution formed in (a) by adding an anti-solvent.
18. A process according to claim 17, wherein the anti-solvent is diisopropyl ether, n-hexane, n-heptane or diethyl ether.
19. A process according to claim 17, wherein the anti-solvent is diisopropyl ether.
- 25 20. A crystalline donepezil hydrochloride sesquihydrate, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 5.1, 10.8, 12.8, 13.3, 13.9, 15.0, 16.3, 17.1, 17.7, 19.5, 20.1, 21.4, 23.2, 24.1, 26.6, 27.3, 28.2, 29.7, 31.9 and 35.3 degrees.
- 30 21. A crystalline donepezil hydrochloride sesquihydrate as defined in claim 20, further characterized by an x-ray powder diffraction spectrum as in figure 4.
22. A process for preparation of donepezil hydrochloride sesquihydrate as defined in claim 20, which comprises the steps of:
- a) dissolving donepezil free base in a mixture of tert-butyl alcohol and water;

- b) adding hydrochloric acid; and
  - c) isolating donepezil hydrochloride sesquihydrate by filtration or centrifugation.
23. A pharmaceutical composition comprising donepezil hydrochloride form H1 of claim 1 and a pharmaceutically acceptable carrier or diluent.
- 5 24. A pharmaceutical composition comprising donepezil hydrochloride form H2 of claim 9 and a pharmaceutically acceptable carrier or diluent.
25. A pharmaceutical composition comprising donepezil hydrochloride monohydrate of claim 12 and a pharmaceutically acceptable carrier or diluent.
- 10 26. A pharmaceutical composition comprising donepezil hydrochloride sesquihydrate of claim 20 and a pharmaceutically acceptable carrier or diluent.